

REMARKS

The Office Action of July 2, 1997 has been carefully considered and the following reply prepared. Claims 1-17 are pending in the application. Claims 1-7, 15 and 16 drawn to non-elected subject matter have been canceled without prejudice. Claims 11 and 12 have also been canceled without prejudice. Claims 8, 13, 14 and 17 have been amended. New claims 18 - 33 have been added. Page 6 of the specification has been amended to correct a typographical error.


Applicants acknowledge the Notice of Draftsperson's Patent Drawing Review, PTO-948. Formal drawings will be submitted when notice of allowable subject matter has been received.

Applicants would also like to bring to the Examiner's attention Applicants' claim for priority under 35 U.S.C. §119. The Office Action Summary page indicates that the certified copy of the priority application was not received. The certified copy of Applicants' priority application 9513180.1 (filed in the United Kingdom on June 28, 1995) was submitted to the Patent and Trademark Office on September 20, 1996. The Examiner's references to the priority application in the Office Action lead Applicants' attorney to conclude that the certified copy was indeed received in the Patent and Trademark Office and that the Office Action Summary is incorrect. Applicants respectfully request that the Examiner check the application file and advise Applicants if the priority application has been received so the situation can be corrected if necessary.

At pages 2 and 3 of the Office Action the Examiner restricted the claims of the application under 35 U.S.C. §121 into four groups. This restriction requirement was also earlier made by telephone on May 23, 1997. Applicants' attorney elected the claims in Group II (claims 8-14 and 17) for prosecution. Applicants affirm the election of the claims of Group II for prosecution.

At page 4 of the Office Action, the Examiner objected to the disclosure of the specification and claims. The Examiner indicated that Applicants had failed to direct insertion of the substitute sequence listing submitted December 10, 1996 and requested direct replacement of the original sequence listing with the corrected sequence listing. Applicants have canceled the originally filed sequence listing and directed insertion of the substitute sequence listing filed on December 10, 1996.

The Examiner also indicated that claim 12 contains a typographical error, "Ganglias". This part of the objection is moot in view of the cancellation of claim 12 without prejudice.




Withdrawal of these objections is respectfully requested.

At page 4 of the Office Action, the Examiner rejected claim 12 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and use the invention. The Examiner stated that enablement of claim 12 requires availability of NCIMB deposit number 40744 and that this determination have been made because the claim specifically recites this deposit and the materials required to construct it have not been shown to be publicly known and freely available.

Applicants respectfully traverse this rejection. Claim 12 has been canceled without prejudice and this rejection is now moot. Withdrawal of this section 112, first paragraph rejection is respectfully requested.

At pages 5-7 of the Office Action, the Examiner rejected claims 8, 11, 13-14 and 17 under 35 U.S.C. §112, first paragraph. The Examiner stated that, while being enabling for SEQ ID NOS:1, 3, 5 and 7 and degenerate sequences encoding the same proteins, the specification does not reasonably provide enablement for other sensory neuron sodium channel proteins which are insensitive to tetrodotoxin. The Examiner further stated that the specification fails to provide any written description of polynucleotides that hybridize to nucleic acids encoding the SNS sodium channel of SEQ ID NOS:1, 3, 5 and 7 or polynucleotides encoding other species of this SNS sodium channel.

Applicants respectfully traverse this rejection. Claim 8 has been amended in accordance with the Examiner's comments to state that the nucleic acid sequences encodes the sodium channel protein selected from the group consisting of SEQ ID NOS: 2, 4, 6 and 8. New claims 30-34 are drawn to specific nucleic acid sequences of claim 8. Claim 11 has been canceled without prejudice and the portion of this rejection relating to the subject matter of this claim is now moot. Claims 13 and 14 have been amended to delete dependency on claim 11 which has been canceled. Claim 17 has been amended to depend from claim 8. New claims 18-20 which depend from claim 9 have been added. New claims 18-20 are drawn to specific sequences in claim 9, SEQ ID NOS: 3, 5 and 7, respectively, which the Examiner has stated are enabled. New claims 21-23 are drawn to vectors comprising the nucleic acid sequence of claims 18, 19 or 20, respectively. New claims 24-26 are drawn to host cells transformed or transfected with a nucleic acid sequence of claims 18, 19 or 20, respectively. New claims 27-29 are drawn to methods of producing a mammalian sensory neuron sodium channel protein which utilize a nucleic acid sequence of claims 18, 19 or 20,



respectively. Withdrawal of this section 112, first paragraph rejection is respectfully requested.

At page 7 of the Office Action, the Examiner rejected claims 8, 11, 13 and 14 under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection contains several parts which will be answered separately.

The Examiner stated that claim 8 is incomplete in depending upon non-elected claims 1-7. Claim 8 has been amended to be an independent claim. Dependence on non-elected claims 1-7 has been deleted.

The Examiner stated that claims 8, 13 and 14 use improper Markush language or are improperly multiply dependent.

Claim 8 has been amended to delete "claims 1-7". Claims 13 and 14 have been amended to delete "claims 8-12" and substitute therefor "claims 8, 9, 10, 18, 19 or 20".

The Examiner further stated that claim 11 is confusing in reciting "to strand of claim 8" as it is unclear if both strands or only the complementary strand is intended.

Claim 11 has been canceled and this part of the rejection is now moot.

In view of the above, Applicants respectfully request withdrawal of this entire section 112, second paragraph rejection.

At page 8 of the Office Action, the Examiner rejected claims 11 and 13-14 under 35 U.S.C. §102(a) as being anticipated by Sangameswaran et al. The Examiner stated that Sangameswaran et al. discloses nucleic acid encoding a tetrodotoxin resistant sodium channel from DRG expressed in *Xenopus* oocytes. The Examiner further stated that the sequence disclosed by Sangameswaran et al. would hybridize to SEQ ID NO:1.

Applicants respectfully traverse this rejection. Claim 11 has been canceled without prejudice. Claims 13 and 14 have been amended to delete dependence on claim 11. This rejection is now moot and withdrawal is respectfully requested.

At pages 8 and 9 of the Office Action the Examiner rejected claims 9, 11 and 13-14 under 35 U.S.C. §102 (a) as being anticipated by Akopian et al. (Nature, 1996). The Examiner stated that inventorship of the instant application is Akopian and Wood, whereas the authorship of the references is Akopian, Sivilotti and Wood, thus making the reference by "others" within the meaning of the statute. The Examiner further stated that Applicant cannot rely upon the foreign priority papers to overcome this rejection because the concept of the hybridizing sequence in claim 11 does not appear to be contemplated in this document. The

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Examiner also stated that the priority document does not clearly demonstrate a correspondence between the sequences disclosed therein and the claimed SEQ ID NOS:3, 5 and 7 and as such claim 9 is entitled to benefit of only the instant application's filing date.

Applicants respectfully traverse this rejection. Akopian et al. reports the identification of a tetrodotoxin-resistant sodium channel, referred to as SNS, which is expressed by sensory neurons. The publication discloses an amino acid sequence for the SNS sodium channel, but does not disclose a nucleic acid sequence coding for the channel. The SNS sodium channel disclosed in this publication is the subject of the present application. Akopian et al. was published in January 1996, after the filing date of Applicants' priority application.

Akopian et al. does not anticipate any of the sequences specified in claim 9, or new claims 18-33. SEQ ID NO: 1 which codes for the SNS sodium channel is disclosed in Applicants' priority application. SEQ ID NO: 7 is a sequencing variation of the SNS sodium channel as described in the specification at page 7. SEQ ID NOS: 3 and 5 encode variants of the SNS sodium channel, as described at page 6 of the specification. Neither of these variants is disclosed in Akopian et al. The sequence of SEQ ID NO: 3 codes for a variant of the SNS sodium channel that has 521 amino acids. This variant of the SNS sodium channel is disclosed in Applicants' priority application. SEQ ID NO: 5 codes for a variant of the SNS sodium channel that contains a 176 amino acid repeat inserted after amino acid 585 in SEQ ID NO: 2. Claim 11 has been canceled without prejudice and the rejection is moot with respect to this claim. Withdrawal of this section 102(a) rejection is respectfully requested.

At page 9 of the Office Action, the Examiner rejected claims 8 and 11 under 35 USC §102(b) as being anticipated by Gautron et al. The Examiner stated that Gautron et al. discloses nucleic acid encoding a sodium channel from DRG that is presumed to have low sensitivity to tetrodotoxin. The Examiner stated that the nucleic acid in Gautron et al. would hybridize to SEQ ID NO:1 under some hybridization conditions.

Applicants respectfully traverse this rejection. Gautron et al. reports isolation and characterization of cDNA encoding the C-terminal portion of a putative glial sodium channel α subunit, referred to in the publication as Na-G. The authors found that Na-G was expressed not only in brain, dorsal root ganglia, and sciatic nerve, but also tissues outside the nervous system, including cardiac and skeletal muscle and lung. This publication discloses only part of the amino sequence of the full length Na-G. No nucleic acid sequence encoding Na-G is disclosed. The claimed sequences encoding the sodium channel protein of SEQ ID NOS: 2, 4, 6, or 8 each code for proteins much longer than the 429 amino acid fragment shown in this



publication. Claim 11 has been canceled without prejudice and the rejection is moot with regard to this claim. Accordingly, since Gautron et al. does not disclose any nucleic acid sequences, and the amino acid sequence of the disclosed Na-G is much shorter than the protein encoded by any of the claimed nucleic acid sequences, Gautron et al. does not anticipate claim 8. Withdrawal of this section 102(b) rejection is respectfully requested.

At pages 9 and 10 of the Office Action, the Examiner rejected claim 11 under 35 USC §102 (b) as being anticipated by Rogart et al. (PNAS). The Examiner stated that Rogart et al. discloses nucleic acid sequences that would hybridize to SEQ ID NO: 1 under some hybridization conditions.

Applicants respectfully traverse this rejection. Claim 11 has been canceled without prejudice. This rejection is now moot and withdrawal is respectfully requested.

In view of the above, the present application is believed to be in a condition ready for allowance. Reconsideration of the application is respectfully requested and an early Notice of Allowance is earnestly solicited.

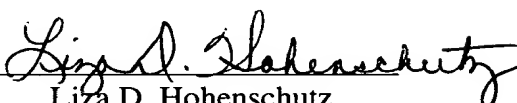
Respectfully submitted,

ZENECA Inc.

Date: December 30, 1997

Docket No.: PHM.70086

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